TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
FP0505		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2005/001840	08.02.2005	09.02.2004

International Patent Classification (IPC) or national classification and IPC

C12Q1/68(2006.01), C12N15/10(2006.01), G01N33/50(2006.01)

Applicant

FUSO PHARMACEUTICAL INDUSTRIES, LTD.

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:

      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2005/001840

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1-29 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

nos. 6-18 as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 1,3,5, 19-20 received by this Authority on 09.12.2005

nos.* _____ received by this Authority on _____

☒ the drawings:

sheets Fig. 1-4 as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☒ the claims, nos. 2, 4

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2005/001840

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1, 3, 5-20	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1, 3, 5-20	NO
Industrial applicability (IA)	Claims	1, 3, 5-20	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: JP 8-173192 A (Hamamatsu Photonics K.K.), 9 July 1996

Document 2: JP 2000-504213 A (Flinders Technologies Pty Ltd.), 11 April 2000

Document 3: WO 01/081541 A2 (Research Development Foundation), 1 November 2001

The inventions set forth in claims 1, 3 and 5 to 18 do not involve an inventive step in the light of documents 1 to 3 cited in the international search report.

Documents 1 to 3 set forth in situ PCR wherein a sample containing cells is immobilized on a support, the nucleic acid contained in said sample is exposed by treatment which uses a surfactant and/or enzymes, the nucleic acid in said sample on said support is amplified, and a judgment is made as to whether the amplified nucleic acid is a target nucleic acid (see, in particular, document 1, claims 1 to 4; document 2, page 13, line 5 to page 26, line 2; document 3, examples 2 and 3).

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Claims 1, 3, 5, 6, 9 to 11 and 18 to 20

At the time of filing of this application, it was a known technique to use a support having separated compartments such as porous plates or strip wells in order to process a large number of samples simultaneously.

In addition, in in situ PCR, the target nucleic acid is detected directly on the sample after PCR, but a judgment as to whether the amplified nucleic acid present in the PCR reaction solution is the target nucleic acid is made in normal PCR, and there is nothing preventing a person skilled in the art from employing a method carried out in normal PCR for the detection of nucleic acid amplified in in situ PCR.

It would therefore be easy for a person skilled in the art to employ a support having separate compartments to process a large number of samples simultaneously and use said support to immobilize cells, and to make the judgment whether the amplified nucleic acid present in the PCR reaction solution is a target nucleic acid, in the in situ PCR set forth in documents 1 to 3.

Claim 7

At the time of filing of this application, it was a known technique in the field of devices for detecting targets on supports to adhere a reagent for detection beforehand to said support, therefore it would be easy for a person skilled in the art to conceive of immobilizing beforehand the gene fragments used for detection on the support of the inventions set forth in documents 1 to 3.

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Claim 8

At the time of filing of this application, it was a known technique to use a DNA micro-array to detect the presence of a target nucleic acid.

It would therefore be easy for a person skilled in the art to conceive of the invention set forth in claim 8 of this application based on the inventions set forth in documents 1 to 3 and said known technique.

Claims 14 to 17

It would be easy for a person skilled in the art to conceive of employing the methods of detecting nucleic acids set forth in documents 1 to 3 to ascertain the presence of genes related to infectious diseases, cancer or hereditary diseases.